UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,144	02/14/2002	Doreen S. Rao	BSC-201 (1002/276)	6889
22852 7590 07/21/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER		EXAMINER		
LLP			MCEVOY, THOMAS M	
901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/075,144	RAO ET AL.				
Office Action Summary	Examiner	Art Unit				
	THOMAS MCEVOY	3731				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>08 Ar</u>	oril 2009					
·= · · · · · · · · · · · · · · · · · ·	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
•	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-12,14,15,17-20,22,23,28-34,36-42,45-53,60-64 and 66-76</u> is/are pending in the application.						
4a) Of the above claim(s) <u>4,5,7,10-12,15,18-20 and 23</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,6,8,9,14,17,22,28-34,36-42,45-53,60-64 and 66-76</u> is/are rejected.						
7) Claim(s) is/are objected to.	,					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage 						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

Application/Control Number: 10/075,144 Page 2

Art Unit: 3731

DETAILED ACTION

1. Currently claims 1-12, 14, 15, 17-20, 22, 23, 28-34, 36-42, 45-53, 60-64 and 66-76 are pending. Claims 4, 5, 7, 10-12, 15, 18-20 and 23 have been withdrawn. Claims 13, 16, 21, 24-27, 35, 43, 44, 54-59 and 65 have been cancelled. Claims 1-3, 6, 8, 9, 14, 17, 22, 28-34, 36-42, 45-53, 60-64 and 66-76 are considered below.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. Claims 1-3, 6, 8, 9, 14, 17, 22, 28-34, 36-42, 45-53, 60-64 and 66-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobita (US 5,669,239).

Regarding claims 1, 3, 17, 22, 36, 45-49, 60-64 and 66-76, Tobita discloses a device for treating a body canal (ear piercing) comprising a device capable of medical use (earrings with straight posts are used to promote healing of ear

piercings; see attached references cited) that includes a proximal end-piece positioned at a proximal-most end of said medical device (sphere at end in Figure 8) and an elongated body portion (member 1/8 and chain from Figure 8). Tobita fails to disclose a distal end-piece positioned at a distal end of said medical device, where the end-pieces have substantially the same non-looped shape. Tobita does disclose that both ends of member 1/8 can have accessory end-pieces (col. 4, lines 9-12; Figure 7). It would have been obvious to one of ordinary skill in the art to have provided the Figure 8 accessory end piece (sphere and chain) at both ends of member 1/8 as an obvious matter of design choice. With this modification, the elongated body portion would be disposed between the proximal end-piece and a distal end-piece and the body portion would comprise a plurality of interconnected loops directly connected to the proximal end-piece and the distal end-piece. The interconnected loops are configured to fit within a body canal, where each of the loops comprises a member defining at least one opening, the member of each loop passing through at least one opening of another loop to form the plurality of interconnected loops. Adjacent interconnected loops are moveable along each of an X, Y, and Z orthogonal axis relative to each other at least during deployment of the medical device in the body canal. The elongated body portion further comprises a substantially cylindrical non-loop segment (member 1 or 8) and would comprise a first end directly connected to a first loop of the interconnected loops and a second end directly connected to a second loop of said interconnected loops. A cross-

sectional diameter of at least one (and therefore both) of the end-pieces is larger than a diameter of a remainder of the medical device (where this claim limitation implies that both end pieces can be the same size). Tobita fails to specifically disclose that the loops are made of a biodegradable material but does disclose that other parts of the device can be made of iron (col. 4, lines 5-8). It would have been obvious to one of ordinary skill in the art to have made other parts of the device, including the loops, out of iron since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. The non-loop segment can be made out of a compressible material such as gold or plastic (col. 4, lines 5-8). Regarding claims 2, 32 and 40, the body portion comprises discrete loops (Figure 8). Regarding claim 6, at least one of the loops is substantially circular (Figure 8). Regarding claims 8, 33, 41 and 52, a member of at least one of the loops comprises a substantially circular cross-section (Figure 8). Regarding claims 9, 34, 42 and 53, at least one of the members comprises a closed loop (Figure 8). Regarding claims 14 and 50, a surface of the body segment is uneven (at 3 or at 10 in Figure 1, for example). Regarding claims 28 and 29, at least one of the endpieces is capable of holding a respective end of the device at a specific anatomical location such as a renal pelvis, a urinary bladder, or a blood vessel. Regarding claim 30, with the above modification, a proximal loop member would be joined to the proximal end-piece and a distal loop member would be joined to the distal end-piece. Regarding claim 31, Tobita does not specifically disclose how the loops are attached

to the end-pieces. However, it is old and well-known in the art that articles of jewelry are connected by welding or soldering. The above well-known in the art statement is taken to be admitted prior art because Applicant failed to traverse Examiner's assertion (MPEP 2144.03). Regarding claim 37, each of the plurality of interconnected loops is configured to move within the confines of the opening of an adjacent loop (Figure 8). Regarding claim 38, the interconnected loops are configured to permit fluid to pass through each at least one opening (Figure 8). Regarding claim 39, an axial length of the body portion is adjustable (by bending and/or compressing the chains or by the Figure 1 mechanism). Regarding claim 51, a portion of the segment (member 8) is substantially tubular (Figure 1). Or the whole segment is tubular inasmuch as Applicant's Figure 2 or 3A segments are.

Response to Arguments

5. Applicant's arguments with respect to the pending claims have been considered but are most in view of the new ground(s) of rejection.

Conclusion

- 6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Shiller (US 3,831,597) teaches that straight earning posts are used to heal ear piercings (col. 1, lines 30-36).
- 7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Application/Control Number: 10/075,144 Page 7

Art Unit: 3731

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/ Examiner, Art Unit 3731

/Anhtuan T. Nguyen/ Supervisory Patent Examiner, Art Unit 3731 7/20/09